

**REMARKS**

Claims 1, and 6, 7 and 10-26 are pending.

Claim 1 was amended to recite all the features of Claim 9, including the features of intervening Claim 8, and to correct antecedent basis for the first coupling. Thus, it is respectfully submitted no new matter or new issues requiring a search are presented by this amendment.

Claims 8 and 9 have been cancelled without prejudice or disclaimer.

It is understood claims 11, 12, 15, 16, 18, 25 and 26 have been withdrawn from consideration at this time. Applicant respectfully submits Claim 1 is generic and requests the non-elected species be rejoined if Claim 1 is found allowable.

I.     Examiner's Interview

Applicant thanks the Examiner for the courtesies extended on April 6, 2006 in a telephonic interview. During the interview the rejections were discussed and the undersigned explained the amendments and arguments of this Amendment After Final.

II.    Claim Amendments

Claim 1 has been amended to include the features presented in previous claims 8 and 9. Claim 24 has been amended to overcome the rejection under 35 USC § 112, as discussed below. No new matter has been entered.

III.   35 USC § 112

Claims 9 and 24 stand rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim that which is considered the invention.

The Office Action asserts claim 9 is unclear because the second coupling is described as being "of the conical type." The Office Action asserts because the drawings allegedly show only one conical coupling, it is not understood if the second coupling *and the first coupling* are both conical. Applicants respectfully present, according to claim 9, *both* the first coupling and the second coupling are conical.

(1) Figs. 1 and 2 show a conical coupling between flange-type insert 15 and upper end 22a of pin means 18 and this is also described at page 7, first paragraph.

(2) Also, the specification at page 7, third paragraph, describes Figs. 1 and 2 as coupling inner sides of the inner cavity of the femoral head 12 and outer sides of the flange-type insert lower portion 15b to form a conical coupling. Thus, although it may be difficult to see in Figs. 1 and 2, these portions are slanted to form this conical coupling.

Also, Applicants direct the Examiner's attention to non-elected Fig. 3. Fig. 3 shows a conical coupling between femoral head 12 and flange-type insert 115, and another conical coupling between flange-type insert 15 and upper end 22a of pin means 18. This can be seen by the tapered sides included in each coupling. Thus, reconsideration is respectfully requested.

The Office Action asserts Claim 24 is unclear due to lack of antecedent basis for the feature "the cone." In response, Claim 24 has been amended, following the Examiner's helpful suggestion, to clarify the cones defined by the respective conical couplings and to eliminate any lack of antecedent basis. Withdrawn Claims 25 and 26 have been similarly amended in the event they are rejoined.

#### IV. 35 USC § 103 - Ficat et al. in view of Townley

Claims 1, 6-9, 13, 14, 17, 19 and 21-24 stand rejected under 35 USC § 103 as allegedly being unpatentable over Ficat et al. (U.S. Patent No. 3,064,645) in view of Townley (U.S. Patent No. 6,096,084). The Office Action asserts Ficat et al. teaches each feature of the claims, except for, *inter alia*, the coupling is conical, a feature allegedly taught by Townley.

Initially, Applicants point out the present invention, as recited by the present claims is a modular prosthesis for a hip which comprises:

- a spindle or pin 18 inserted inside the bone of a femur 11;
- a head or cap 12 having a cavity therein, able to articulate in a mating acetabular seating 13; and
- a flange-type insert 15, intermediate between the pin and the head, and able to be

coupled and anchored,

(ii) wherein an outer part 15b of the flange-type insert 15 is able to be coupled and anchored to the inner cavity 14 of the spherical cap 12 by a conical coupling (page 7, lines 12-15); and

(i) wherein an inner seating of the flange-type insert 15 is able to be coupled and anchored to an upper protruding end 22a of the pin 18 by another conical coupling (see page 7, lines 1-6).

It should be noted the reference numerals are provided for exemplary purposes only, and are not intended to limit the claims in any form.

The first and the second conical couplings can be either coaxial (page 7, lines 15-17, see figures), angled (page 9, lines 5-7) or offset and parallel with each other (page 9, lines 13-15).

The Office Action asserts it would have been obvious to one of ordinary skill in the art to use a conical coupling, as allegedly taught by Townley. However, even if Townley were to teach a conical coupling to attach stem 200 to head 100, there is neither a teaching nor suggestion in the cited references to employ *a conical coupling* to connect the femoral head to a flange-type insert, as well as *another conical coupling* to connect the flange-type insert to a pin means engaged in a top portion of the femur, as recited by claim 1.

The two conical couplings, as recited by the present claims permit a rigid and stable anchoring (not movable and slidable, as will be explained below when referring to the patent of Ficat et al.) between the head (12) and the flange-type insert (15-115), by means of the interference between the conical perimeter of the inner cavity (14) of the head (12) and the conical outer perimeter of the flange-type insert (15-115).

Contrary to the description of Ficat et al., the conical (mating) configuration of the inner perimeter of the inner cavity (14) of the head (12) and of the outer perimeter of the flange-type insert (15, 115) (see page 7, lines 12-15; page 8, lines 5-9) of the presently claimed invention allows rigidly and definitively mounting the head (12) on the flange-type insert (15, 115) after coupling the flange-type insert (15, 115), by means of another conical coupling, to the protruding part of the pin (18) inserted in the femur (see page 10, lines 30-31, page 11, lines 1-2).

With this structure and configuration, all the advantages and the features broadly described in the present specification - see for example from page 8, line 10, to page 9, line 2, or page 9, lines 16-19 - can be obtained.

A. The Combination of Ficat et al. and Townley is Inoperative

Ficat et al. teaches, "The chief feature of our improved damped prosthesis consists in that its spherical hollow articular section includes two caps made of Stellite, assembled so as to allow a suitably limited compression, the damping means being constituted by a core made of an elastomer enclosed inside said spherical section without any contact with any living tissue" (col. 1, lines 42-47).

Moreover Ficat et al. continues, "the damped head (which is made in two different pieces, one fixed and the other movable, as explained thereafter) is secured in the two above-mentioned cases through screwing over the spindle adapted to carry it, which allows providing interchangeable heads..." (col. 2, lines 15-18).

In other words, Ficat et al discloses a structure for a hip prosthesis comprising:

- a spindle 1 having a cylindrical tube 7 projecting upwards and outwardly threaded;
- a lower cap 8 comprising a central bore 12 which is inwardly threaded in order to be screwed to the cylindrical tube of the spindle 1, thus anchoring the lower cap 8 to the spindle 1; and

- an upper cap 11 coupled to the lower cap 8 in the manner showed in Figure 4, which is importantly, "with a clearance between the edge 15 of the cap 11 and the bead 10" (col. 3, lines 41-42), so the upper cap 11 is adapted to move towards the spindle up to the stop defined by the bead 10 due to the stresses to which the prosthesis is subjected (col. 3, lines 50-54).

In other words, if the bead 10 of Ficat et al is considered the flange 15 of the present claims, it is clear that, for accomplishing the actual and aimed function which the damped prosthesis of Ficat et al. is designed for, the bead 10 can not anchor and fix of the head, as in contrast does the present invention. Ficat et al. requires the bead 10 to end the travel and stop the downwards stroke of the head when it is subjected to a force of compression, as described in Ficat et al. in col. 3, line 54.

Therefore, Applicants respectfully present lower cap 8 of Ficat et al. does not anchor the spherical head, as currently recited for the coupling means of the present claims.

In Ficat et al. the head 11 must be able to slide with respect to the coupling element when subjected to compression forces to permit the head to “float” over the coupling element. This floating is assisted by the elastomer which Ficat et al. injects into the head through central tapped bore 12 (See, col. 3, lines 25-29 and 39-54).

Anchoring the lower cap 8 to the articular cap 11 would nullify the required damping effect of the prosthesis. In other words, to replace the floating coupling of the lower cap 8 to the articular cap (femoral head) 11 of Ficat et al. with a conical coupling which anchors the femoral head renders the required floating function inoperative. Thus such a modification is improper.

B. Ficat et al. and Townley Combined Does Not Teach Two Conical Couplings

Townley does not make up for the deficiencies of Ficat et al. Townley does not disclose the presently claimed coupling of a flange-type insert between the pin means and the femoral head to: (i) couple the flange-type insert to the pin by one conical coupling, and (ii) anchor the femoral head to the flange-type insert by another conical coupling.

As discussed above, the device of Ficat et al. does not anchor the head to the coupling means with a conical coupling or any other means. Rather, Ficat et al. allows floating for a certain stroke toward and away from the femur. Moreover, the device of Ficat et al. employs only a threaded coupling between the intermediate element 8 and the upper end of the spindle.

Townley discloses a single direct coupling between the upper end of the pin 200 and the (solid, i.e., with no cavity) spherical head 100. Therefore, Townley can not obtain all the advantages of the presently claimed structure. Particularly, Townley can not obtain the two-time application broadly disclosed on page 11 of the present specification.

Assuming Ficat et al. and Townley are combined (and Applicant even disputes this) the combination at most replaces the threaded coupling of the spindle 1 to the lower cap 11 of Ficat et al. with a conical coupling. This combination does not result in the presently claimed additional conical coupling between the inner perimeter of the mating cavity of the femoral head and the outer perimeter of the flange-type insert.

V. 35 USC § 103 - Ficat et al. in view of Townley and Callaway et al.

Claim 10 stands rejected as being unpatentable over Ficat et al. in view of Townley and further in view of Callaway et al. (US 6,736,852). It is respectfully submitted Callaway et al. does not make up for the above-described deficiencies of Ficat et al. and Townley.

Moreover, because the head of Ficat et al. has to be filled with elastomer through bore 12, the screw of Callaway et al. can not be used.

VI. 35 USC § 103 - Ficat et al. in view of Townley and Pappas et al.

Claim 20 stands rejected as being unpatentable over Ficat et al. in view of Townley and further in view of Pappas et al. (US 5,030, 342). It is respectfully submitted Pappas et al. does not make up for the above-described deficiencies of Ficat et al. and Townley.

VII. Conclusion

In view of the above it is respectfully submitted all objections and rejections are overcome. Thus, a Notice of Allowance is respectfully requested.

Respectfully submitted,

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